UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,266	06/01/2005	Yasuo Tano	124098	1045

25944 7590 06/20/2011

OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
06/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com
jarmstrong@oliff.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,266	TANO ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 10, 2011 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support within the specification for the claim limitation "...a plurality of electrodes each of which are configured to...stick in an optic papilla of an eye before a bundle of nerve fibers exit the eye to form an optic nerve..." in combination with the other elements in the claim since there is no support within the specification that said electrodes are implanted at a specific location relative to the optic papilla BEFORE a bundle of nerve fibers exit the eye. The specification only provides support that said electrodes directly stimulate the optic nerve consisting of a bundle of the nerve fibers (e.g., pp 3, lines 16-20 of the specification) and/or that

the electrodes are stuck into the optic papilla to stimulate the optic nerve, while avoiding the nerve fibers and blood vessels (e.g., pp 9, lines 1-6).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yagi (US 2004/0102843) in view of de Juan, Jr. et al. (US 5,109,844) and Krulevitch et al. (US 2003/0097166).

Yagi discloses an artificial vision system (e.g., Fig 1, 1) comprising: an external device to be disposed outside a body of a patient (e.g., Fig 1, 2); an image pickup device (e.g., Fig 1, 4); and an image processing device (e.g., Fig 1, 9) which is configured to generate a stimulation signal by processing an image captured by said image pickup device; an internal, implanted device (e.g., Fig 1, 3) including: a receiving device which is configured to receive a stimulation

pulse signal and convert it into an electrical stimulation pulse signal (see Figure 1, 'reception'); and a plurality of electrodes {e.g., via the disclosed electrode unit 19 that carries the electrodes 11 that are each transmit an electrical signal to the retina [0059] & (Figs 1 & 5(a))} and are further configured to output the electrical stimulation pulse signal that is generated based on the image captured by the image pick up device thereby enabling the patient to visually recognize the image captured by said image pick up device(e.g., [0028]-[0030], [0053]-[0054] & [0059]).

Yagi discloses the claimed invention having an artificial vision system including a plurality of electrodes except wherein said system includes electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye before a bundle of nerve fibers exit the eye to form an optic nerve and a plurality of signal wires which individually connect each said electrode from outside to inside of the eye and the receiving device covered with an insulating material with high biocompatibility and a tube for configured to bundle the plurality of signal wires together. De Juan, JR et al. teaches that it is known to use a method and device for stimulating a retinal ganglion cell in the retina of a patient, wherein said device comprises a stimulating electrode array (e.g., element 72) that is located adjacent to the surface of the retina, positioned at a ganglion cell , i.e. at a location within the papilla of an eye before a bundle of nerve fibers exit the eye to form an optic nerve [e.g., (col 2, ln 10-24), (col 7, ln 49-63) & (Fig 7)]. Note that the optic papilla is the portion of the optic nerve formed by retinal ganglion cells axons as they enter said optic nerve, in which the optic papilla is the location of the eye along the pathways of the optic nerve. Krulevitch et al. teaches that it is known to use a needle-like electrode array (e.g., see Fig 14a) that can be used for artificial vision in which said system comprises a plurality of conductive lines and/or leads

(e.g., elements 16 & 23) patterned into the substrate of the electrode array (e.g., elements 21) and are further connected to the electrodes of the substrate (e.g., elements 22), wherein said conductive lines and/or leads are bundled together via a flexible, ribbon cable (e.g., element 24) that is used to connect said electrodes to the electronics of the artificial vision device, such as a component used for transferring an image signal to tissue in a retina {e.g., [0085] & (Figs 6 & 10)}. Note that the Examiner is interpreting the disclosed conductive lines and/or leads (e.g., elements 16 & 23) as being the plurality of signal wires which individually connect each electrode to the receiving device, in which the Examiner further notes that it is well known to those of skill that said conductive lines and/or leads are insulated via an insulative material, as is instantly claimed in order to selectively deliver and/or receive electrical energy via the electrodes and to safely provide electrical coupling between circuitry and said electrodes via a means that avoids exposing bodily tissue to stray and/or harmful energy. Also note that the Examiner is interpreting the disclosed ribbon cable (e.g., element 24) as being the claimed foldable tube used for bundling the plurality of signal wires together into one (e.g., see Fig 10) since the disclosed cable provides a flexible means of "bundling" the conductive leads together into a singular form so as to electrically couple the disclosed electrodes to the electronics of the device, in which it is known in the art that a cable comprises a centrally disposed opening and/or lumen means in which said leads are disposed and bundled within. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Yagi with the needle electrode array adapted to be disposed adjacent to the surface of the retina, positioned at a ganglion cell, i.e. at a location within the papilla of an eye before a bundle of nerve fibers exit the eye to form an optic nerve as taught by De Juan, JR et al. and the plurality of

wires bundled together via a ribbon connector means as taught by Krulevitch et al., since such a modification would provide the artificial vision system including a plurality of electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye and a plurality of signal wires which individually connect each said electrode and the receiving device covered with an insulating material with high biocompatibility being bundled together via a foldable tube for providing the predictable results pertaining to providing an electrode array used to penetrate and provide electrical stimulation into the optic nerve of a patient for effectively making electrical contact with retina ganglion cells in retina without penetrating the retinal basement membrane at the surface of the retina, i.e. at a point within the papilla of the eye before a bundle of nerve fibers exit the eye to form an optic nerve [e.g., de Juan, Jr. et al. (col 2, ln 10-24), (col 7, ln 49-63) & (Fig 7)], and providing the results pertaining to providing an electrode cable comprising a plurality of wires suitable for use as an electrical connection between an electrical stimulating device and connectable to the proximal end of the cable and needle-like electrode(s) connected to the distal end of the cable, wherein said plurality of wires are shielded from stray electrical energy that may be harmful to a patient by way of an insulative, tubular sheath {e.g., Krulevitch, [0085] & (Fig 10)}.

Response to Arguments

4. Applicant's arguments with respect to claim 7 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments, filed May 10, 2011, with respect to the objections of the specification and the 112, first paragraph claim rejections have been fully considered and are persuasive and have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICOLE F. LAVERT/
Examiner, Art Unit 3762